UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, *ex rel.* JAMES ALLEN, Plaintiff, v. GUIDANT LLC, formerly doing business as GUIDANT CORPORATION, GUIDANT SALES LLC, formerly doing business as GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., and BOSTON SCIENTIFIC CORPORATION, Defendants.	)	Civ. No.: 11-cv-22 (DWF/AJB)

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR
MOTION TO DISMISS RELATOR'S CLAIMS

I. OVERVIEW

This *qui tam* case was filed in 2008 by Relator, James Allen, on behalf of the United States under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et. seq.* Under that statute, the government sought and was granted leave to intervene in this case in December 2010 and, in January 2011, filed its Complaint in Intervention. Defendants Guidant LLC, Guidant Sales LLC, Cardiac Pacemakers, Inc. and Boston Scientific Corporation ("Defendants") now seek dismissal of Relator's claims.[1]

[1] Defendants moved on September 24, 2010 to dismiss Relator's Amended Complaint, then pending before the U.S. District Court for the Western District of New York. That motion was still pending when the United States moved to intervene and to transfer this matter to this court on December 14, 2010. The New York court granted both of the government's motions, but did not rule on Defendants' dismissal motion

Defendants' motion should be granted because: (1) Relator's putative FCA claims are based on publicly available information for which Relator is not an original source, thus depriving the Court of subject matter jurisdiction over Relator's putative claims; (2) Relator lacks standing to assert common-law claims on behalf of the United States; (3) those of Relator's claims not adopted by the government in its Complaint in Intervention are properly dismissed based on the filing of that Complaint and Relator's subsequent failure to prosecute his unique claims; and (4) Relator fails to plead fraud with the particularity required by Fed. R. Civ. P 9(b).

II. BACKGROUND

Information concerning short-circuiting in PRIZM 2 and RENEWAL devices has been in the public domain since mid-2005, when the New York Times published an article highlighting the case of a young man whose death was attributed to this problem. *See Maker of Heart Device Kept Flaw From Doctors*, N.Y. Times, May 24, 2005, at A1 (attached as Exhibit A) ("The matter has come to light after the death of a 21-year old college student from Minnesota, Joshua Oukrop, with a genetic heart disease. Guidant acknowledges that his device, known as a defibrillator, short-circuited"); *Defective Heart Devices Force Some Scary Medical Decisions*, N.Y. Times, June 20, 2005, (attached as Exhibit B) (reporting that Guidant was "recalling … the Contak Renewal and the Contak Renewal 2, because they could also potentially short-circuit"). The May 24, 2005 article specifically identified the "Ventak Prizm 2 Model 1861" as being affected by the short-

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before transferring this case to this Court. This motion supersedes Defendants' prior motion to dismiss.

circuiting problem. *Id.* The article also chronicled how Guidant changed its manufacturing process in April and November 2002 to address the problem but allegedly concealed facts from doctors, patients and the FDA while continuing to sell devices from existing inventory. *Id.*

Additional print and broadcast news reports followed, including a follow-up *Times* article that reported that, "in April 2002 [Guidant] increased the spacing between a wire and a device component after determining that electricity could potentially arc between them and cause a short circuit." *Heart Device Sold Despite Flaws, Data Shows*, N.Y. Times, June 2, 2005, at C4 (attached as Exhibit C). That article also reported "Guidant made another change by adding extra insulation around the component, which is called the backfill tube." *Id*.

During this same time period, Guidant issued widely-publicized Patient Safety Advisories for the PRIZM 2 and RENEWAL devices. The government also acted, classifying the Company's Patient Safety Advisories as recalls and, on July 1, 2005, issuing its own Update. The FDA's Update reported:

> [Guidant's] investigation determined these devices can develop an internal short circuit when attempting to deliver an electrical shock to the heart, preventing the treatment of abnormal heart rhythms. The problem is caused by deterioration of electrical insulation in the device and can only be detected after the device has already malfunctioned.

FDA Updates Consumers on Guidant Corporation's Implantable Defibrillators, U.S. Food & Drug Administration, July 1, 2005, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108456.htm

(last visited September 27, 2011) (attached as Exhibit D) ("FDA Update"). All of these activities were intended to, and did, receive substantial publicity.

The media coverage and government actions triggered a wave of highly publicized litigation. Relator was a part of that wave. On April 4, 2006, over two years before Relator filed his Original Complaint in this action, he filed a personal injury suit in New York state court, which not only echoed the Times' reporting, but also foreshadowed the allegations he would later make in this case:

> For several years prior to and up through and including February 2002, defendants became aware of an electrical shorting defect in certain models of ICDs, including the one known as the VENTAK PRIZM II DR Model 1861. Specifically, GUIDANT knew that the electrical insulation of the device could deteriorate and cause an electric malfunction.
>
> GUIDANT reportedly changed its manufacturing process on or about April 16, 2002, and made further manufacturing changes on or about November 13, 2002, in an attempt to correct this electrical shorting defect.
>
> GUIDANT did not notify the FDA of the manufacturing changes made in November 2002 until it submitted its next Annual Report to the FDA in August 2003. Further GUIDANT intentionally omitted telling physicians and/or patients implanted with such devices, including the plaintiff and his physicians.
>
> Despite the fact that defendants knew that VENTAK PRIZM II DR Model 1861 devices manufactured prior to November 2002 contained a defect that caused electric shorting and electrical failure of the device, defendants failed to act to protect patients.

Allen v. Guidant Corp., Civ. No. 1:06-cv-00219-WMS (N.Y. Sup. Ct. 2006) (Product Liability Compl. ¶¶ 34-37) (attached as Exhibit E).

Relator's state court personal injury case was removed to federal court and then transferred to the MDL docket of this Court for coordinated pretrial proceedings. The MDL Master Complaint – of which Relator's personal injury claims were a part – told the same story, referencing and borrowing from the New York Times reporting. *See* Plaintiffs' Master Complaint for Personal Injury, Economic Loss, Third Party Payor and Medicare Secondary Payor Act Claims, Including Class Actions, *In re: Guidant Implantable Defibrillators Products Liability Litigation*, Civ. No. 05-1708 (DWF/AJB) (Docket Entry No. 132) (D. Minn. April 24, 2006) (hereinafter "MDL Master Complaint") (attached as Exhibit F). For example, among the MDL Master Complaint's allegations related to the PRIZM 2 device are the following:

> The Ventak Prizm 2 DR 1861 has a potentially fatal defect that can cause short circuiting due to deterioration of a wire insulator with the lead connector block, or header, of the device. The short circuit prevents the Ventak Prizm 2 DR 1861 from providing the necessary and appropriate therapeutical [sic] shocks to correct a heart rhythm.
>
> …
>
> Guidant's Ventak Prizm 2 DR 1861s manufactured [sic] are uniformly defective in that they suffer a deterioration of electrical insulation, which will eventually cause the devices to short circuit and fail to function. …
>
> In or before February 2002, Guidant learned that Ventak Prizm 2 DR 1861s were short circuiting when attempting to build a charge to deliver a therapeutic shock. Specifically, Guidant knew that electricity could arc between a lead wire and the backfill tube in the Ventak Prizm 2 DR 1861.

> …
>
> …Guidant modified the manufacturing specifications and process of the Ventak Prizm 2 DR 1861 to increase the spacing between the feedthru wire and the backfill tube through injection of additional medical adhesive into the device.
>
> In November 2002, once again without FDA approval or any contemporaneous disclosure to the FDA, the medical community, or the public, Guidant made further modifications to the manufacturing specifications and process of the Ventak Prizm 2 DR 1961 to thicken the insulation on the backfill tube.

MDL Master Compl. ¶¶ 85, 90, 93, 95-96. *See also* MDL Master Compl. ¶¶ 116-133 (containing allegations relating to the RENEWAL devices).

In 2007, the parties to the MDL reached a global resolution. Relator's personal injury case – which covered only his PRIZM 2 device and did not include any FCA allegations – was settled and dismissed as a part of that resolution. On July 10, 2008, Relator filed his first *qui tam* Complaint against Guidant. Relator's Amended Complaint followed two years later on July 22, 2010. Like his personal injury complaint and the MDL Master Complaint, Relator's Original and Amended Complaints in this case referenced the well-publicized events of 2005 and before; and they echoed allegations in the MDL Master Complaint that Guidant's allegedly fraudulent omissions and misrepresentations were designed to, and did, lead to government reimbursement for PRIZM 2 and RENEWAL devices which would not have occurred had the devices' life-threatening defects been known. *Compare* MDL Master Compl. at ¶¶ 85, 90, 93, 95-96 *with* Relator's Am. Compl. at ¶¶ 4-5, 44, 115, 117-118, 123-124 (detailing Guidant's

alleged attempts to remedy the effects in the PRIZM 2 through manufacturing and design changes and Guidant's alleged failure to inform the FDA and public); *and compare* MDL Master Compl. at ¶¶ 83, 119, 243-244, 252, 308 *with* Relator's Am. Compl. at ¶¶ 37, 44, 59, 60, 61, 108-111, 113, 115, 117-118, 121, 129, 124, 136 (alleging that Guidant's fraudulent omissions and misrepresentations were designed to, and did, cause patients to purchase Guidant devices, which they otherwise would not have purchased had they known of the devices' life-threatening defects).[2] In short, both of Relator's complaints in this case repeated the allegations at the heart of Relator's personal injury case and the MDL which, in turn, had chronicled and relied upon the publicly available information and government actions from 2005 and before.

III. ARGUMENT

A. RELATOR'S CLAIMS FAIL TO ESTABLISH JURSIDCTION UNDER THE FCA BECAUSE THEY ARE BASED ON PUBLICLY DISCLOSED INFORMATION

Relator cannot satisfy the jurisdictional requirements set forth in the FCA because his claims are subject to what is commonly known as the public disclosure bar. *See* 31 U.S.C. §3730(e)(4). Because Relator bases his claims on media reports and other materials in the public record, they constitute what are described as "parasitic claims" and are insufficient to establish jurisdiction under the Act. *United States ex rel. Costner v. URS Consultants, Inc.*, 153 F.3d 667, 675 (8th Cir. 1998) (*citing United States ex rel.*

[2] In particular, paragraphs 119, 243-244 and 252 in the MDL Master Complaint expressly allege Guidant defrauded Medicare in connection with the PRIZM 2 and RENEWAL devices.

Rabushka v. Crane Co., 40 F.3d 1509, 1511 (8th Cir. 1994) (*subsequent history omitted*)). More specifically, this Court lacks subject matter jurisdiction over Relator's claims because they are, in the words of the FCA's public disclosure bar, "based upon" a "public disclosure" and Relator is not the "original source" of the information. As a result, the Court should dismiss Relator's Amended Complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

The party invoking federal jurisdiction under the FCA bears the burden of proving, on a claim-by-claim basis, that subject matter jurisdiction exists by a preponderance of the evidence. *Hays v. Hoffman*, 325 F.3d 982, 987 (8th Cir. 2003); *see also Rockwell Int'l Corp. v. United States*, 127 S. Ct. 1397, 1406 (2007) (reaffirming the jurisdictional nature of 31 U.S.C. § 3730(e)(4)). By its terms, the FCA's public disclosure bar is an issue of subject matter jurisdiction, providing:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions [1] in a criminal, civil, or administrative hearing; [2] in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation; or [3] from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (emphasis added).

If there has been a public disclosure, to be an "original source," an individual must have "direct and independent knowledge of the information on which the allegations are based and [have] voluntarily provided the information to the Government before filing an action under [31 U.S.C. § 3730] which is based on the information." 31 U.S.C. §

3730(e)(4)(B). Fed. R. Civ. P. 12(b)(1) requires dismissal of a case when the court lacks jurisdiction over the subject matter.

The Eighth Circuit has adopted a three-part test to analyze this jurisdictional issue: "(1) Have allegations made by the relator been 'publicly disclosed' before the *qui tam* suit was brought? (2) If so, is the *qui tam* suit 'based upon' the public disclosure? and (3) If so, was the relator an 'original source' of the information on which the allegation was based?" *Minnesota Ass'n of Nurse Anesthetists v. Allina Health Systems Corp.*, 276 F.3d 1032, 1043 (8th Cir. 2002). An examination of each of these elements confirms that Relator's Amended Complaint is the archetypical "parasitic" FCA claim, and should be dismissed for lack of jurisdiction.

1. *Relator's Allegations Were Publicly Disclosed Before He Brought His* Qui Tam *Suit.*

There is no question that the allegations Relator makes here were publicly disclosed before he filed. The disclosures at issue occurred in 2005; Relator's first *qui tam* filing was in 2008. Indeed, the Amended Complaint is at least the fourth pleading iteration of Relator's allegations against Guidant - the first being Relator's individual product liability complaint in early April 2006, and the second being the MDL Master Complaint a few weeks later. All of these complaints were based on prior news reports, government actions, prior litigation and other publicly available materials.

2. *Relator's Allegations Are Based on Previously Disclosed Public Information.*

Courts will consider a *qui tam* suit to be "based upon" a public disclosure whenever the allegations in the suit are "derived from" or "supported by" the disclosure, regardless of where the relator obtained his information. *Minnesota Ass'n of Nurse Anesthetists,* 276 F.3d at 1047; *see also United States ex rel. Mistick PBT v. Hous. Auth.*, 186 F.3d 376, 385 (3d Cir. 1999) (recognizing that all circuits other than the Fourth Circuit have held that "based upon" means "supported by" or "substantially similar to").

There can be no dispute that the "derived from" or "supported by" test is met here as the essential allegations in Relator's action are virtually identical to allegations made in prior complaints, reports and the media. The Amended Complaint echoes the core allegations that appeared in the New York Times articles (and other news reports) and the prior litigation; namely, the PRIZM 2 and RENEWAL devices (1) contained defects that caused them to short-circuit; and (2) Guidant's efforts to remedy the defects were unsuccessful. *See, e.g.,* Am. Compl. ¶¶ 45-48 (use of polyimide tubing "to address the potential of the device to short circuit and malfunction"); ¶ 59 ("Guidant was aware that the manufacturing design changes were intended to correct arcing and other electrical defects . . . ."); and ¶ 108 ("In February 2002 Guidant concluded there was the potential for electrical short circuiting in the PRIZM 1861 defibrillator which adversely affected its efficiency and safety").

The Amended Complaint similarly mirrors the allegations in the MDL Master Complaint, namely the allegations that Guidant defrauded the FDA in regards to the

PRIZM 2 and RENEWAL devices, MDL Master Compl. ¶¶ 84-133, and that, as a result of Guidant's conduct, Medicare was defrauded. MDL Master Compl. ¶¶ 243-244, 252 (alleging, inter alia, that Guidant (1) "directed its tortious conduct with respect to the Devices to Medicare" (2) "pursued a means of wrongfully passing on to Medicare costs resulting from the Devices" and (3) had a "wrongful plan to pass on to Medicare the full costs of replacement for its defective devices").

The public disclosure bar does not require a showing that every fact supporting a relator's allegations of fraud was publicly disclosed before the relator filed his lawsuit. Rather, allegations in a *qui tam* action are considered publicly disclosed when they share a substantial identity with the publicly disclosed allegations. *Minnesota Ass'n of Nurse Anesthetists*, 276 F.3d at 1047. The public disclosure bar thus requires merely a showing that the prior public disclosure was "sufficient to put the government on notice of the likelihood of related fraudulent activity." *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 389 (6th Cir. 2005); *see also United States ex rel. Settlemire v. District of Columbia*, 198 F.3d 913, 919 (D.C. Cir. 1999).

The facts in *Gilligan* are strikingly similar to those here. *Gilligan* involved allegations about pacemaker leads. *Gilligan*, 403 F.3d at 388. In the mid-1990s, two lawyers filed a series of product-liability suits against Medtronic alleging, among other things, that the devices should never have been approved for sale and that Medtronic obtained FDA approval only by providing false and fraudulent evidence to the agency. *Id.* Based on information obtained through those product-liability actions (which were

publicly filed and litigated), the lawyers later filed an FCA action against Medtronic. The FCA allegations were that Medtronic had caused "false claims" to be submitted by certifying that its medical devices were approved for sale by the FDA; plaintiffs argued FDA approval was automatically revoked because Medtronic had obtained the agency's approval through fraud. *Id.* at 390-91.

The *Gilligan* court held that the prior products liability litigation triggered the public disclosure bar, and that the district court therefore lacked jurisdiction. *Id.* The court determined that the government could reasonably have inferred the FCA fraud from the prior complaints, including allegations of design changes and fraud on the FDA. *Id.* at 390-91. The Court found that although FCA allegations were not included in the products liability litigation, because the FCA Medicare fraud claim necessarily relied on the FDA fraud claim the prior public disclosure requirement was satisfied; "the disclosed fraud [put] the government on notice of the 'possibility of fraud' surrounding the product or transaction" *Id.* at 390-91. The case here is even stronger. Unlike *Gilligan*, here the underlying products liability action – in which Relator participated – specifically addressed Guidant's alleged fraud upon Medicare. *See* MDL Master Complaint ¶¶ 243-246. Accordingly, the government had even more direct notice of Relator's putative fraud claims here than it did in *Gilligan*, which triggered the public disclosure bar based only on the "possibility of fraud."

3. *Relator Does Not Qualify as an Original Source*.

Where the allegations or transactions at issue were publicly disclosed, as they were in this case, a *qui tam* relator may avoid dismissal under the jurisdictional bar only by establishing that the relator was an "original source of the relevant information." *U.S. ex rel. Kinney v. Stoltz*, 327 F.3d 671, 674 (8th Cir. 2003).

An original source is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). "A relator has direct knowledge when he sees it with his own eyes." *Kinney*, 327 F.3d at 674; *see United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995). Independent knowledge means "knowledge not derived from the public disclosure." *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1048; *see Barth*, 44 F.3d at 703. The FCA "is intended to encourage individuals who are either close observers or involved in the fraudulent activity to come forward, and *is not intended to create windfalls for people with secondhand knowledge of the wrongdoing."* *Kinney*, 327 F.3d at 674, citing, *Hays v. Hoffman*, 325 F.3d 982, 986-87 (8th Cir. 2003) (emphasis supplied). This latter description precisely fits Relator.

Relator has absolutely no direct or independent knowledge concerning the design or manufacture of the PRIZM 2 and RENEWAL devices nor of Guidant's modifications

[3] There is no doubt that the government was exceedingly familiar with the MDL products liability action. As part of the resolution of that matter, Medicare recovered several million dollars via the Medicare Secondary Payor Statute. 42 U.S.C. § 1395y(b).

to the devices. *See* Am. Compl. ¶ 80 (referencing "Relator's research"); ¶¶ 45-48 (referencing Guidant's Post-Approval Annual Report); ¶¶ 62-63 (referencing Guidant's letter to physicians); ¶¶ 78-79 (referencing Guidant's Adverse Event Reports); and ¶ 81 (referencing Guidant's Medical Device Safety Information and Corrective Action letter to physicians). Rather, Relator simply compiled public information and reframed it as an FCA claim. This is precisely what the public disclosure bar prohibits; such "knowledge" is neither direct nor independent. "[A] person who obtains secondhand information from an individual who has direct knowledge of the alleged fraud does not himself possess direct knowledge and therefore is not an original source." *Barth*, 44 F.3d at 703 (citing *Hays*, 325 F.3d at 990–91). *See also United States ex rel. Findley v. FPC–Boron Emps. Club*, 105 F.3d 675, 688 (D.C. Cir. 1997) (finding "[a] relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed"); *United States ex rel. Kreindler & Kreindler*, 985 F.2d 1148, 1159 (2d Cir. 1993) (holding that "[a]lthough Kreindler conducted, as counsel, the litigation that resulted in public disclosure of information concerning Black Hawk helicopters upon which Kreindler relies to bring the *qui tam* action, UTC and its employees were the original sources of the information disclosed in that litigation").

Relator's purported "research" and "investigation" based on third-party information, prior litigation and government reports clearly disqualifies him as an original source. Similarly, Relator's speculation as to what allegedly caused the claimed

design defects of the PRIZM 2 and RENEWAL devices fails to make him as an original source: neither his purported collateral research and investigations, nor his personal hypotheses about what should be concluded from publicly disclosed information qualify him as an original source of information able to sustain a *qui tam* claim on behalf of the Government. *See Barth*, 44 F.3d at 703; *U.S. ex rel. Kreindler & Kreindler*, 985 F.2d at 1159; *New York Med. Coll.*, 252 F.3d 118, 121-22 (2d Cir. 1995). "Federal jurisdiction over a private FCA action is not created simply by arguing that the review of publicly disclosed information spurs plaintiffs to advance a different theory. Such an argument, based solely on publicly available information, could no more support a federal lawsuit to advance an alternative theory regarding the assassination of President Kennedy, or whether men ever actually landed on the moon." *U.S. ex rel. Reynolds v. Science Applications Int'l Corp., et al.*, 2008 WL 2566747 (SDNY 1008).

The Amended Complaint's allegations are based upon publicly disclosed information for which Relator cannot qualify as an original source. Accordingly, under the public disclosure bar of the FCA, this Court lacks subject matter jurisdiction over Relator's FCA claim, which must be dismissed with prejudice.

B. RELATOR'S COMMON-LAW CLAIMS MUST BE DISMISSED FOR LACK OF STANDING

In his Second and Third Causes of Action, Relator purports to bring claims on behalf of the United States for unjust enrichment and payment by mistake of fact. *See* Am. Compl. ¶¶ 137-145. Plaintiff cites no authority to establish that he has standing to

bring such claims on behalf of the United States and, indeed, there is none. As explained in *United States ex rel. Phipps v. Comprehensive Community Development Corp*., "[w]hile the FCA gives a relator the right to bring an action for a violation of the FCA, the FCA 'does not give relators the right to assert common-law claims on behalf of the United States.'" 152 F. Supp. 2d 443, 452 (S.D.N.Y. 2001) (quoting *United States v. Eastman Kodak Co.*, 98 F.Supp.2d 141 (D. Mass. 2000) (citing *United States ex rel. Long v. SCS Bus. & Tech. Inst.*, 999 F.Supp. 78, 92 (D.D.C.1998), *rev'd on other grounds*, 173 F.3d 870 (D.C. Cir. 1999)). *See also United States ex rel. Laucirica v. Stryker Corp.*, 2010 WL 1798321 (W.D. Mich. May 3, 2010) (same); *United States ex rel. Bender v. North American Telecommunications, Inc.*, 686 F.Supp.2d 46 (D.D.C. 2010) (same); and *United States ex rel. Rockefeller v. Westinghouse Elec. Co.*, 274 F.Supp.2d 10, 14 (D.D.C. 2003) (same).

C. THE UNITED STATES' COMPLAINT SUPERCEDED RELATOR'S COMPLAINT

In December 2010, the United States exercised its right to intervene and take over this litigation from Relator.[4] Rather than adopting Relator's Amended Complaint, however, the United States crafted its own Complaint in Intervention setting forth the Government's theories for holding Guidant liable under the False Claims Act and common-law claims. The filing of the United States' Complaint in Intervention resulted in Relator's Amended Complaint being entirely superseded and rendered "without legal

[4] *See* 31 U.S.C. § 3730(b)(4)(A) (providing that the Government controls the action if it chooses to intervene); and § 3730(c)(1) (providing that if the Government intervenes, it has primary responsibility for prosecuting the action).

effect." *United States ex rel. Alsaker v. Centracare Health Sys., Inc.*, 2002 U.S. Dist. LEXIS 10180, at *6 n.2 (D. Minn., June 5, 2002).

In *Alsaker*, the relators filed their complaint, after which the government intervened and filed an "amended complaint." The defendant later moved to dismiss several counts of the United States' complaint and all the counts of the relators' complaint. The Court, in a footnote, ruled that:

> [a]lthough defendants also move to dismiss all counts of the relators' complaint, only the amended complaint is legally relevant. 'It is well-established that an amended complaint supersedes an original complaint and renders the original complaint without legal effect.' [citations omitted]. The government concedes as much in its response brief. . . .

Alsaker, 2002 U.S. Dist. LEXIS 10180, at *6 n.2. *See also* John T. Boese, 1 Civil False Claims and Qui Tam Actions, § 4.05[B] at 4-174-175 (3d ed. 2006) ("Because the amended complaint filed by the Justice Department upon intervening supersedes the original pleading, the relators' complaint should be formally dismissed, for although dual representation exists, there is ultimately only one plaintiff") (footnote omitted).

In this case, once the government filed its Complaint in Intervention, Relator was required to take steps to either sever those additional claims he wished to pursue from the United States' complaint, or file his own new complaint on those claims not adopted by the government. *See United States ex rel. Prawer & Co. v. Fleet Bank of Maine*, 1995 U.S. Dist. LEXIS 16095 (D. Me. 1995) (noting that the government elected to pursue its case against less than all the defendants named in the action by relator and that the parties agreed the proper procedure was to "sever the action" into two parts). Relator took no

such steps. As the time to file amended complaints has now passed, Relator's superseded claims are "without legal effect" and are properly dismissed under Rule 12(b).

D. RELATOR'S ALLEGATIONS FAIL THE PARTICULARITY REQUIREMENTS OF RULE 9(B) APPLICABLE TO FCA CLAIMS.

In contrast to a motion challenging subject matter jurisdiction, when ruling on a motion to dismiss under Rule 12(b)(6) for "failure to state a claim upon which relief can be granted," the court looks to the four corners of the complaint and is required to accept the plaintiff's allegations as true and to construe those allegations in the light most favorable to the plaintiff. *Owen v. Gen. Motors Corp.*, 533 F.3d 913, 918 (8th Cir. 2008). Even so, complaints alleging fraud – including complaints alleging FCA violations – must satisfy the "heightened bar" of Rule 9(b) and be pleaded with particularity. *Brown v. Medtronic, Inc.*, 628 F.3d 451, 459 (8th Cir. 2010).

Because Relator has failed to meet the particularity requirements of Rule 9(b), his claims should be dismissed with prejudice.

1. *The Amended Complaint Fails to Identify a Single False Claim as Required to Satisfy Rule 9(b).*

Relator's FCA claims are subject to the heightened pleading requirements of Fed. R. Civ. P 9(b). *United ex rel. Joshi v. St. Luke's Hospital, Inc.*, 441 F.3d 552, 556 (8th Cir. 2006) (holding that because the False Claims Act is an anti-fraud statute, complaints alleging FCA violations must comply with Federal Rule of Civil Procedure 9(b)) (citing *United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 674 (8th Cir. 2003)). More specifically,

> Under Rule 9(b), "the circumstances constituting fraud ... shall be stated with particularity." Rule 9(b)'s "particularity requirement demands a higher degree of notice than that required for other claims," and "is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations." *United States ex rel. Costner v. URS Consultants, Inc.*, 317 F.3d 883, 888 (8th Cir. 2003) [citation omitted]. To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result. *See, e.g., Corsello* [*v. Lincare, Inc.*], 428 F.3d [1008,] 1012 [(11th Cir. 2005)]; *Schaller Tel. Co. v. Golden Sky Sys., Inc.*, 298 F.3d 736, 746 (8th Cir. 2002). Put another way, the complaint must identify the "who, what, where, when, and how" of the alleged fraud. *Costner*, 317 F.3d at 888 (citing *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 550 (8th Cir. 1997)).

Id.

The Eighth Circuit has also ruled that if a complaint, like Relator's Complaint here, "alleges a systematic practice of submitting fraudulent claims, the FCA complaint 'must provide some representative examples of [the] alleged fraudulent conduct,' specifying 'the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result.'" *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009) (quoting *Joshi*, 441 F.3d at 556-57).

Relator's Amended Complaint, however, does not: (1) identify a claim; (2) state the who, what, when, where or how of the claim; (3) identify any fraudulent statement in

the claim; or (4) explain why the statement was fraudulent. *See generally* Am. Compl. Rather, Relator alleges generally that a certain number of "unapproved" or "investigational" PRIZM 2 and RENEWAL devices were implanted, estimates that a certain percentage of the implantation procedures occurred in the United States, and further extrapolates an estimate of how many of these procedures might have been paid for by the United States. Am. Compl. ¶¶ 116, 125-26.

The only procedures specifically identified by Relator are: (1) his own PRIZM 2 replacement procedure on December 5, 2005, which he concedes was paid for by a private insurance company and thus cannot constitute a false claim to the government; and (2) the implantation of five devices at various Veterans' Administration hospitals between September 2002 and January 2003. *See* Am. Compl. ¶¶ 75-76, 127. Relator does not, however, identify a *claim* for payment for any of these devices and certainly not the "who," "what," "when," "where," or "how" of any false or fraudulent claim.

Roop is instructive because, as in this case, the relator there alleged that a medical device manufacturer sold defective medical equipment to third parties who then submitted claims for reimbursement to Medicare. The *Roop* relator also alleged that the medical device manufacturer "knew [the devices] were defective and failed to file reports of defects required by the Food and Drug Administration's Medical Device Reporting regulations, which caused Medicare to pay countless fraudulent reimbursement claims submitted by Hypoguard distributors." *Roop*, 559 F.3d at 820. Despite the relator's detailed allegations, the district court ruled that the complaint failed to satisfy Rule 9(b)

because the relator did not allege that the devices failed to comply with any statute or FDA regulation, and did not identify a single false claim. *United States ex rel. Roop v. Hypoguard USA, Inc.*¸ 2007 WL 2791115, *2-3 (D. Minn. 2007) ("*Roop I*"). The court also found that the relator failed to satisfy Rule 9(b) because he failed to provide details regarding causation:

> Roop asserts that Hypoguard caused the submissions of false claims by selling products the FDA would not have approved but for Hypoguard's fraudulent submission in the pre-market approval process. … This claim also fails to meet the particularity requirements of Rule 9(b). Although Roop contends that Hypoguard provided the FDA with false information during the pre-market approval process, Roop does not allege who within Hypoguard provided the FDA with false information, what the allegedly false information was, or when that information was provided to the FDA (including the date, time, and place).

Id. at *2.

Relator here has done no better. He provides no information concerning any claim for payment for the five devices he identifies. He does not even allege that the devices are PRIZM 2 or RENEWAL devices. He merely alleges that the five devices were "[a]mong the universe of devices which were sold and implanted for which the Veterans Administration paid claims." Am. Compl. ¶ 127. Relator, moreover, does not allege when, if ever, a claim for payment was presented to the government for these devices, the dates they were submitted, their content or, most importantly, why the claims were false. Relator's "allegations" are merely conclusory assumptions that lack any factual substantiation. Relator, as in *Roop*, makes conclusory accusations that Guidant provided

the FDA with false information but fails to "allege who within [the company] provided the FDA with false information, what the allegedly false information was, or when that information was provided to the FDA (including the date, time, and place)." *Roop* at *2. Accordingly, his complaint must be dismissed pursuant to Rule 9(b).

IV. CONCLUSION

The Court lacks jurisdiction over Relator's Amended Complaint. The allegations are subject to the public disclosure bar and Relator cannot qualify as an original source. Moreover, Relator lacks standing to assert common-law claims on behalf of the government. Even if the Court could exercise jurisdiction here, Relator's claims are properly dismissed because they have been superseded by the government's intervention and Relator has failed to either sever his putative claims or amend before the time for doing so expired. Finally, the claims are properly dismissed because they fail to satisfy the particularity requirements of Rule 9(b).

WHEREFORE, Defendants request that the Court dismiss Relator's Amended Complaint with prejudice for lack of subject-matter jurisdiction, lack of standing, and failure to state a claim upon which relief can be granted, and grant such other and further relief to which the Court may feel Defendants are entitled.

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s/Michael L. Koon
Michael L. Koon
Missouri Bar # 51481 (*pro hac vice*)
Attorney for Defendants
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard

Kansas City, MO 64108
Telephone: (816) 559-2285
Facsimile: (816) 421-5547
E-mail: mkoon@shb.com

Rachel A. Simek
D.C. Bar # 498109 (*pro hac vice*)
David T. Fischer
D.C. Bar # 472236 (*pro hac vice*)
Attorneys for Defendants
SHOOK, HARDY & BACON L.L.P.
1155 F Street, NW, Suite 200
Washington, DC 20005-2004
Telephone: (202) 783-8400
Facsimile: (202) 783-4211
E-mail: rsimek@shb.com
dfischer@shb.com

James L. Volling
Minnesota Bar # 113128
Leif T. Simonson
Minnesota Bar # 389764
Attorneys for Defendants
FAEGRE & BENSON LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, Minnesota 55402
Phone: (612) 766-7000
Fax: (612) 766-1600